WHASC – Animal Final Report

Date: 6 Jan 2016

1. Protocol Number: FWH20140109A

2. Type of Research: Animal

3. Title: Evaluation of Endografts in the Setting of Noncompressible Torso Hemorrhage in swine *(Sus Scrofa)*

4. Principal Investigator (PI):

Name	Rank	Date of IACUC Training	Branch of Service/ Corps	Staff Resident Fellow Civilian	Department / Office Symbol	Email (if other than WHASC Outlook)	Phone	Pager
Brandon Propper, MD	O-5	2/10/2014	USAF	Staff	59th MDW	Brandon.w.propper.mil@mail.mil	210-916-1174	N/A

5. Purpose: The most difficult injuries to manage in austere condition are those labeled as noncompressible torso hemorrhages. The use of endografts have been described for thoracic and abdominal aortic injuries. A quickly deployable endograft may be a lifesaving maneuver in injuries that may otherwise yield a preventable death. This protocol assessed the feasibility of utilizing newer endograft technology that has not been used to repair traumatic injury to seal a large non-compressible arterial injury.

6. Results: We have found that we were able to seal the rupture sites with the endovascular device in all but one animal. Failure to achieve seal in this animal was related to user error and not device malfunction. We consider this a success in terms of achieving our primary endpoint of seal of vascular injury. In addition, we were able to learn how this current technology behaves in vivo when used for traumatic injury and not for age related disease. We furthered current literature and can confirm that placement of this technology is rapid and feasible in the emergent setting.

7. How may your findings benefit the Air Force? Noncompressible torso hemorrhage continues to be the leading cause of potentially survivable trauma on the battlefield based on a review of OIF and OEF. This type of technology is reported in the US and Europe for use in aortic rupture for age related injury, but never been tested for traumatic injury. The advantage of this particular endovascular technology is that a limited inventory of sizes are needed, as a single device can treat a wide spectrum of aortic sizes. This differs greatly from other current endovascular grafts. Additionally, the device deploys rapidly with limited steps for full deployment. While the results of this project cannot be immediately translated into CPG, these results highlight a success of an existing technology to treat non-compressible torso hemorrhage. Expanding this technology may allow for treatment of other arterial beds, but to our knowledge this technology is limited to aortic use currently. Future studies will aim and survival models or treatment of differing arterial beds that are commonly injured in wartime trauma (axillary, femoral, ect).

8. Number of Animals

Projected Enrollment of Animals at the Beginning of Study: 54 (Decreased to 39 after amendments)

Actual Number of Animals Enrolled: 29. After a mid review, I believe that the use of additional animals is not likely to alter the outcome. We have achieved successful results in 28/29 animals with one user maldeployment that accounts for the one failure. Since we are not trying to show a difference between two groups, I believe we can abort additional deployments as a cost savings and to limit animal sacrifice.

9. Status of Animals Entered Into the Protocol: Completed

10. Status of Funds: Funds have been obligated and expended as proposed

11. Reason for Closure: Project completion

12. Specific Problems: 1 device mal-deployment. This was user error as we deployed the device higher than the rupture. This is unlikely occur clinically as more advanced imaging is available, but using our fixed C-arm we missed one rupture.

13. Publications and Presentations:

Presentations: considering option for national trauma or vascular surgery meetings

N/A

Publications:
Manuscript in progress

14. Exceptional Achievements:

15. Signature of Principal Investigator: